Health Canada Santé Canada

GUIDANCE DOCUMENT

Management of Disinfectant Drug Applications (2018)

Published by authority of the
Minister of Health

Effective Date	2018/01

Health Products and Food Branch

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice – Gestion des présentations de désinfectants assimilés aux drogues

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Publication date: February 2018

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Cat.: H13-9/5-2018E-PDF
ISBN: 978-0-660-24805-9
Pub.: 170429

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Document Revision History

File name	Guidance Document: Management of Disinfectant Drug Applications (2018)	**Replaces**	Guidance Document: Management of Disinfectant Drug Applications (2014)
Effective Date	2018/01	**Effective Date**	2014/01

Version	**Location of Change**	**Change Made**	**Effective Date**
1	Not applicable	Initial Issuance of Guidance	2014/01
2	Some revisions throughout document	Removal of references to contact lens disinfectants, and high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices	2018/01

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INTRODUCTION

1.1 Policy Objectives

The purpose of this guidance document is to outline the way Health Canada will manage submissions for market authorization for disinfectants regulated as drugs submitted in accordance with the *Food and Drug Regulations*. It also outlines the responsibilities and expectations for applicants of disinfectant drug submissions before and throughout the application review process.

1.2 Policy Statements

Applicants must provide Health Canada with sufficient information to support the safety, efficacy and quality of a disinfectant drug when used in accordance with the label's recommended conditions of use before market authorization can be granted.

Health Canada must evaluate this information and determine whether a drug identification number (DIN) should be issued.

1.3 Scope and Application

This guidance document applies to products regulated as drugs under the *Food and Drugs Act* and *Regulations* that are represented for use as:

- disinfectants for use on non-critical medical devices and hard non-porous environmental surfaces and inanimate objects in domestic, industrial/institutional, hospital, food processing and/or barn premises, referred to as "hard surface disinfectants", and that additionally may indicate hard non-porous food and non-food contact surface sanitizer claims on their labelling, in which case they are referred to as "disinfectant-sanitizers".

All disinfectants regulated as drugs must meet the general safety, efficacy, and quality requirements outlined in the Guidance Document Disinfectant Drugs (2018), except where otherwise noted, as well as the labelling requirements set out by the *Food and Drugs Act* and *Regulations*. In addition, they must meet the specific safety and efficacy requirements outlined in the guidance document:

- Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs (2014)

Appendix 1 of this guidance document provides information regarding the applicable regulatory frameworks for chemical products intended for use on environmental surfaces and inanimate objects (e.g., cleaners, sanitizers and disinfectants), and the associated contact information for the responsible regulatory bodies.

GUIDANCE FOR IMPLEMENTATION

The information in this section outlines the drug application streams applicable to disinfectant drugs. Information regarding the performance standards applicable to these application streams may be found in the following Health Canada document:

- Guidance for Industry: Management of Drug Submissions

1.0 General Application Requirements

Information regarding the submission requirements for a disinfectant drug application may be found in the following Health Canada documents:

- Guideline on Preparation of DIN Submissions
- Guidance Document: Fees for the Review of Drug Submissions and Applications

1.1 General Considerations for Disinfectant Drug Applications

The following information provides clarification on the information being requested for disinfectant drugs:

For the declaration of Active Ingredients and the Non-Medicinal Ingredients on the HC/SC 3011 *Drug Submission Application Form*: The sum of the percent nominal concentrations of the active ingredients and non-medicinal ingredients declared in sections 56 and 57 for the formulated product should total 100%, and should be expressed as a percentage on a weight-per-weight basis (% w/w).

2.0 Administrative Applications

This application stream is applicable to products that do not require a scientific review prior to market authorization. There are three types of administrative applications:

a) Change in Manufacturer/Sponsor's Name: may be due to a merger/buyout, a company name change or a transfer of ownership;
b) Change in Product Name: may involve either a change in the product name with the original drug identification number (DIN) being retained, or the request for an additional product name with a new DIN to be issued; and
c) Licensing Agreement: involves an agreement between two companies, whereby one company supplies a drug product to another company for sale under the second company's name (also referred to as a cross-referenced application, or copy product).

For information regarding administrative application requirements, the following Health Canada documents should be referenced:

- Policy: Assignment of Drug Identification Number (DINs) According to Product Name
- Guidance Document Administrative Processing of Submissions and Applications: Human or Disinfectant Drugs

3.0 Monograph Applications

This type of application stream is applicable to products that do not require a scientific review prior to market authorization, and allows for an abbreviated review process for disinfectants that have a well characterized safety and efficacy profile under specific conditions of use and labelling requirements (e.g., defined active ingredients; dosage; intended use, directions for use, and warnings).

4.0 Full Review Applications

When a proposed product or its labelling is outside the scope of a published Monograph, applicants are required to submit evidence to Health Canada to support the safety, efficacy and quality of the product when used in accordance with the label directions; these applications require a scientific assessment as part of their market authorization.

5.0 Post-Authorization Division 1 Change (PDC) Notification

For products regulated under Division 1 of the *Food and Drug Regulations* that have received market authorization, applicants are permitted to make various post-market changes through the post-authorization Division 1 change (PDC) notification process, and should consult the following Health Canada document:

- Guidance Document on Post-Drug Identification Number (DIN) Changes

Applicants should notify Health Canada within 30 days of making a permitted change.

5.1 Considerations for Changes to the Recommended Premises for Hard Surface Disinfectants

The following information provides clarification on the change identified in the post-drug identification number (DIN) change guidance document as #6 - *Addition, removal or change to the recommended premises for a disinfectant drug*.

The recommended premises (i.e., drug use areas) for disinfectants are chosen by applicants during the market authorization process by selecting the appropriate drug use areas on the HC/SC 3011 *Drug Submission Application Form* (i.e., domestic, industrial/institutional, hospital, food processing, barn, medical instruments, or any combination of these). Applicants seeking to amend the recommended premises for a product following its market authorization should take note of the following situations to determine whether a PDC notification would be appropriate for the proposed change:

a) **Addition of type of premise (e.g., product originally approved only for domestic use, and applicant wants to add industrial/institutional uses)**: This change is not acceptable through the notification process, and therefore a review application is required to proceed with the proposed change.

b) **Removal of type of premise (e.g., product originally approved for both domestic and industrial/institutional uses, and applicant wants to remove the domestic uses):** This

change is acceptable through the notification process, provided that the product label is revised to remove all uses of the product within that premise.

c) **Addition, change or removal of references to specific areas, surfaces or objects within authorized premises**: This change is acceptable through the notification process, provided that the areas, surfaces and/or objects are appropriate for the authorized types of premises.

6.0 New Drug Submission (NDS) Applications

When a proposed product meets the definition of "new drug" as per Part C, Division 8 of the *Food and Drug Regulations* (e.g., contains a new active ingredient or a new combination of active ingredients, or is intended for a new use or indication), then a new drug submission (NDS) application or a supplement to a new drug submission (SNDS) is required. The submission of evidence to Health Canada for both of these types of applications is required to support the safety, efficacy and quality of the product when used in accordance with the proposed conditions of use.

It is recommended that applicants of proposed disinfectant drugs which fall into the NDS or SNDS category request a pre-submission meeting prior to filing an application with Health Canada, as outlined in the Guidance to Industry: Management of Drug Submissions. The purpose of a pre-submission meeting is to discuss the data requirements considered necessary to support the application, and additionally such meetings:

- Familiarize Health Canada review staff with the application prior to its arrival; and
- Provide an opportunity for the applicant to obtain feedback regarding areas of concern identified by Health Canada review staff (i.e., whether the proposed supporting data is considered adequate to establish the safety, efficacy and quality of the drug).

7.0 Post Notice of Compliance (NOC) Changes Notifications

For products regulated as "new drugs" under Part C, Division 8 of the *Food and Drug Regulations* that have received market authorization, applicants are permitted to make various post-market changes, and should consult the following Health Canada documents:

- Guidance Document - Post-Notice of Compliance (NOC) Changes: Framework Document
- Guidance Document - Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document
- Guidance Document - Post-Notice of Compliance (NOC) Changes: Quality Document

These guidance documents provide criteria to determine what is meant as a "significantly different" change, and provide applicants with the data recommendations considered necessary to enable Health Canada to make an accurate determination of the impact of a change to the safety, efficacy and quality of the drug.

EFFECTIVE DATE

This guidance document will come into effect 90 days following the date of publication. All disinfectant drug submissions received after the effective date are expected to be filed with the updated supporting data requirements. Data reports which have been signed off as completed prior to the effective date of this guidance document will be assessed at Health Canada's discretion for their acceptability under the updated data requirements.

APPENDIX

Appendix 1: Regulation of Chemical Products for Use on Environmental Surfaces and Inanimate Objects

In Canada, chemical products represented for use on environmental surfaces and inanimate objects (e.g., cleaners, sanitizers and disinfectants) may be regulated under a number of different frameworks, according to their represented use or purpose. The following table and sections provide general information regarding the different product classes, their corresponding legislation and responsible regulatory body, and examples of their represented uses.

Product Class	Legislation and Responsible Regulatory Body	Examples of Represented Uses
Disinfectant Drugs	*Food and Drugs Act* *Food and Drug Regulations* Natural and Non-prescription Health Products Directorate Health Canada	• Hard surface disinfectants • Hard surface disinfectants with hard non-porous food contact and non-food contact surface sanitizer claims
Pest Control Products	*Pest Control Products Act* *Pest Control Products Regulations* Pest Management Regulatory Agency Health Canada	• Non-food contact surface sanitizers • Soft surface sanitizers • Greenhouse disinfectants • Swimming pool and spa disinfectants
Consumer Products	*Canada Consumer Product Safety Act* *Consumer Chemicals and Containers Regulations* Consumer Product Safety Directorate Health Canada	• Cleaning products for use by consumers
Controlled Products	*Hazardous Products Act* *Controlled Products Regulations* National WHMIS Office Health Canada	• Cleaning products for use in work places
Incidental Additives	*Food and Drugs Act* *Food and Drug Regulations* Food Directorate Health Canada	• Hard surface disinfectants for use in food processing facilities • Food contact surface sanitizers

Product Class	Legislation and Responsible Regulatory Body	Examples of Represented Uses
Non-Food Chemicals	*Food and Drugs Act* *Food and Drug Regulations* Canadian Food Inspection Agency	• Hard surface disinfectants for use in federally registered food establishments • Sanitizers for use in federally registered food establishments

1.0 Disinfectant Drugs

Most chemical products represented for disinfectant uses on hard, non-porous environmental surfaces and inanimate objects are regulated by Health Canada as disinfectant drugs under the *Food and Drugs Act* and *Regulations*.

Chemical products regulated as disinfectant drugs may also be represented for use as food-contact or non-food contact sanitizers on hard, non-porous environmental surfaces and inanimate objects; these products are referred to as "disinfectant-sanitizers".

Disinfectant drugs require a pre-market assessment and issuance of a drug identification number (DIN) prior to being sold in Canada. As part of the pre-market assessment, the efficacy, safety and quality of the drug is evaluated, and as a condition of market authorization applicants are required to submit draft labelling for assessment to Health Canada.

Inspectors monitor and enforce the compliance of disinfectant drugs through post-market regulatory activities under the purview of Health Canada's Health Products and Food Branch Inspectorate.

For information regarding the pre-market authorization requirements for disinfectant drugs, inquiries should be directed to the:

Natural and Non-prescription Health Products Directorate
Health Products and Food Branch
Health Canada

2.0 Pest Control Products

Chemical products represented for use as non-food contact sanitizers on hard, non-porous environmental surfaces and inanimate objects without any associated disinfectant drug claims are regulated as pest control products by the Pest Management Regulatory Agency under the *Pest Control Products Act* and *Regulations*.

Chemical products which are represented for use as disinfectants or sanitizers on porous surfaces and inanimate objects (e.g., carpets, fabrics and textiles) are regulated as pest control products. These products may also be represented for disinfectant drug uses provided that they have also been authorized for use as disinfectant drugs (i.e., a drug identification number has been issued).

Chemical products represented for disinfectant uses in controlling plant pathogens (e.g., greenhouse disinfectants) and for uses in swimming pools or spas are regulated as pest control products and not as disinfectant drugs.

Pest control products require a pre-market assessment and issuance of a registration number prior to being sold in Canada. As part of the pre-market assessment, the efficacy, safety and quality of the product is evaluated, and as a condition of market authorization applicants are required to submit draft labelling for assessment to the Pest Management Regulatory Agency.

Inspectors monitor and enforce the compliance of pest control products through post-market regulatory activities.

For information regarding the pre-market authorization requirements for pest control products, inquiries should be directed to the:

Pest Management Regulatory Agency
Health Canada

3.0 Consumer Cleaning Products

Chemical products intended for use on environmental surfaces and inanimate objects that do not make an expressed antimicrobial activity claim on their label are regulated as cleaners; those represented for use by consumers (i.e., for non-commercial purposes) are regulated as consumer products under the *Canada Consumer Product Safety Act* and the *Consumer Chemicals and Containers Regulations*. Cleaning products may contain recognized antimicrobial ingredients (e.g., sodium hypochlorite, quaternary ammonium compounds, hydrochloric acid) as part of their formulation, however in the absence of an expressed antimicrobial claim a product is regulated as only a cleaner.

There is no requirement for the pre-market approval of consumer cleaning products; however as a condition of sale suppliers are required to appropriately label products with hazard symbols and standardized wording as specified in the *Consumer Chemicals and Containers Regulations*, and to perform mandatory reporting and record keeping as specified in the *Canada Consumer Product Safety Act*.

Inspectors monitor and enforce the compliance of consumer cleaning products through post-market regulatory activities under the purview of Health Canada's Consumer Product Safety Directorate.

For information regarding the legislative requirements for consumer cleaning products, inquiries should be directed to the:

Consumer Product Safety Directorate
Healthy Environments and Consumer Safety Branch
Health Canada

4.0 Workplace Cleaning Products

Chemical products intended for use on environmental surfaces and inanimate objects that do not make an expressed antimicrobial activity claim on their label are regulated as cleaners; those represented for use in Canadian workplaces are regulated as controlled products under the *Hazardous Products Act* and the *Controlled Products Regulations*. Cleaning products may contain recognized antimicrobial ingredients (e.g., sodium hypochlorite, quaternary ammonium compounds, hydrochloric acid) as part of their formulation, however in the absence of an expressed antimicrobial claim a product is regulated as only a cleaner.

There is no requirement for the pre-market approval of workplace cleaning products; however as a condition of sale suppliers are required to meet the hazard communication standards of the Workplace Hazardous Materials Information System (WHMIS).

Compliance activities relating to work place cleaning products are conducted through Health Canada and the provincial, territorial and federal agencies responsible for occupational health and safety.

For information regarding the legislative requirements for workplace cleaning products and the WHMIS hazard communication standards, inquiries should be directed to the:

National WHMIS Office
Health Canada

5.0 Incidental Additives

Incidental additives are chemical products used in food processing facilities which are often not intended to come into direct contact with food but which may potentially become residues in food. They are evaluated by the Bureau of Chemical Safety within Health Canada's Food Directorate under the authority of the *Food and Drugs Act* and *Regulations*.

Within the *Food and Drugs Act* and *Regulations* there is no mandatory requirement for the pre-clearance of incidental additives prior to their use in food processing plants, however there may be certain use conditions where pre-market clearance may be a mandatory requirement under other legislation and certification programs. Manufacturers intending to supply their chemical products to food processors are encouraged to contact the Bureau of Chemical Safety for clarification regarding whether a mandatory pre-market clearance is required. When the pre-market clearance is not mandatory, manufacturers may request that a voluntary evaluation of their product be conducted to determine the acceptability of using the intended incidental additives in food processing plants. If a product is considered by the Bureau of Chemical Safety to be safe for its intended uses, a No Objection Letters (NOL) is issued which can be presented by the manufacturer to prospective food processors.

Sanitizers used on surfaces or inanimate objects that may come into direct contact with food or beverages, also called food contact surface sanitizers, are considered to be incidental additives,

and the Bureau of Chemical Safety is the regulatory body within Health Canada responsible for reviewing their safety.

For information regarding the evaluation requirements for incidental additives and for guidance regarding their appropriate labelling, inquiries should be directed to the:

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch
Health Canada

6.0 Non-Food Chemicals

Chemical products (such as disinfectants, sanitizers, cleaners), used in federally registered meat establishments and that are not intended to become part of the food, are considered to be non-food chemicals. The Canadian Food Inspection Agency (CFIA) deals with the safe use of non-food chemicals in federally registered meat establishments.

Manufacturers intending to supply their chemical products to federally registered meat establishments are encouraged to contact the Canadian Food Inspection Agency for clarification regarding whether a mandatory evaluation of the acceptability of the product for its intended uses is required.

For further information regarding the use of non-food chemicals in meat plants, inquiries should be directed to the:

Canadian Food Inspection Agency